

Issuing Date: 03-Jan-2019

Revision Date: 24-Nov-2021

1. Identification**Product identifier**

SDS Number: BXU533005
Product Name: Cytarabine

Other means of identification

Synonyms: 4-Amino-1-beta-D-arabinofuranosyl-2(1H)-pyrimidinone;
4-amino-1-[(2R,3S,4R,5R)-3,4-dihydroxy-5-(hydroxymethyl)oxolan-2-yl] pyrimidin-2-one;
4-amino-1-[(2R,3S,4S,5R)-3,4-dihydroxy-5-(hydroxymethyl)oxolan-2-yl]-1,2-dihydropyrimidin-2-one; Cytosine beta-D-arabinofuranoside

Recommended use of the chemical and restrictions on use

Product Use: Antineoplastic Agent.
Product Type: Raw material
Uses advised against No information available

Details of manufacturer or importer

Baxter Healthcare Pty. Ltd.
1 Baxter Drive
Old Toongabbie NSW 2146 Australia
Telephone : (02) 98481111

Emergency telephone number

Australia: 1 800 229 837 and Poison Information Centre 13 11 26
Verisk 3E Global Incident Response Hotline +1 760 476 3962; Access Code 335625

2. Hazard(s) identification**GHS Classification**

Germ cell mutagenicity	Category 2 - (H341)
Reproductive toxicity	Category 2 - (H361)
Effects on or via lactation	Yes - (H362)

Label elements

Signal word
Warning

Hazard statements

H341 - Suspected of causing genetic defects
H361 - Suspected of damaging fertility or the unborn child
H362 - May cause harm to breast-fed children

Precautionary Statements - Prevention

Obtain special instructions before use
 Do not handle until all safety precautions have been read and understood
 Use personal protective equipment as required
 Do not breathe dust/fume/gas/mist/vapors/spray
 Avoid contact during pregnancy/while nursing
 Wash face, hands and any exposed skin thoroughly after handling
 Do not eat, drink or smoke when using this product

Precautionary Statements - Response

IF exposed or concerned: Get medical advice/attention

Precautionary Statements - Storage

Store locked up

Precautionary Statements - Disposal

Dispose of contents/container to an approved waste disposal plant

Other hazards which do not result in classification

May be harmful if swallowed.

General Hazards

No information available

3. Composition/information on ingredients

Chemical Name	CAS No.	Weight-%
Cytarabine 147-94-4	147-94-4	>98

4. First-aid measures

Description of first aid measures

General Advice

Treat symptomatically and supportively.

Inhalation:

If inhaled, remove to fresh air. If not breathing, give artificial respiration. If breathing is difficult, give oxygen. Get medical attention.

Eye contact:

In case of contact, immediately flush eyes with plenty of water for at least 15 minutes. Get medical attention.

Skin contact:

In case of contact, immediately flush skin with plenty of water. Get medical attention.

Ingestion:

Do NOT induce vomiting unless directed to do so by medical personnel. Never give anything by mouth to an unconscious person. Get medical attention.

Most important symptoms and effects, both acute and delayed

Contains a known or suspected mutagen. Contains a known or suspected reproductive toxin. May cause harm to breast-fed children.

Indication of any immediate medical attention and special treatment needed

Treat symptomatically. See patient package insert in shipping carton for complete information.

5. Fire-fighting measures

Suitable Extinguishing Media

Use extinguishing media suitable for surrounding materials.

Specific hazards arising from the chemical

No information available

Special protective actions for fire-fighters

Fire fighters should wear positive pressure self-contained breathing apparatus (SCBA) and full turnout gear.

6. Accidental release measures

Personal precautions, protective equipment and emergency procedures

Keep unnecessary personnel away. Use suitable protective equipment (Section 8). Follow all fire fighting procedures (Section 5).

Environmental precautions

See Section 12 for environmental precautions.

Methods and material for containment and cleaning up

Methods for Containment:

If emergency personnel are unavailable, contain spilled material.

Methods for cleaning up:

Shovel or sweep up. Place spilled material in an appropriate container for disposal. Clean contaminated surface thoroughly.

Precautions to prevent secondary hazards

Prevention of secondary hazards Clean contaminated objects and areas thoroughly observing environmental regulations.

7. Handling and storage

Precautions for safe handling

Technical measures/precautions: Avoid production of dust. Avoid skin contact. Avoid eye contact. Do not ingest. Wash thoroughly after handling.

Conditions for safe storage, including any incompatibilities

Technical measures and storage conditions: Keep containers tightly closed in a cool, well-ventilated place. Store at room temperature between 20°C and 25°C (68°F and 77°F). Store in original container.

Incompatible materials: Strong oxidizers.

8. Exposure controls/personal protection

Control parameters

Exposure Limits This product, as supplied, does not contain any hazardous materials with occupational exposure limits established by the region specific regulatory bodies.

Chemical Name	Australia_nohsc :	ACGIH TLV
Cytarabine - 147-94-4	-	-

Appropriate engineering controls

Engineering Measures Provide general or local exhaust ventilation. Open handling must be limited.

Individual protection measures, such as personal protective equipment

Eye/face protection Safety glasses with side-shields are recommended for laboratory and manufacturing use.

Skin and body protection Work uniform or laboratory coat. Additional body garments should be used based upon the task being performed (e.g., sleevelets, apron, gauntlets, disposable suits).

Hand protection Use chemical resistant, impervious gloves.

Respiratory protection In the case of respirable dust, use self-contained breathing apparatus.

9. Physical and chemical properties

Information on basic physical and chemical properties

Physical state:	Solid.
Appearance:	Crystalline powder
Color:	White to off-white
Odor:	No information available
Odor Threshold:	No information available
pH:	No information available
Melting point / melting range:	414-415 °C
Boiling point / boiling range:	No information available
Flash point:	No information available
Evaporation rate:	No information available
Flammability (solid, gas):	No information available
Flammable limits in air-upper (%):	No information available
Flammable limits in air-lower (%):	No information available
Vapor pressure:	No information available
Vapor density	No information available
Density:	No information available
Solubility:	Slightly soluble in ethanol. Slightly soluble in chloroform. Slightly soluble in methanol.
Partition coefficient (n-octanol/water):	No information available
Autoignition temperature:	No information available
Decomposition temperature	No information available
Viscosity:	No information available
Explosive Properties:	No information available
Oxidizing Properties:	No information available

Other information

Molecular weight: 243.22

10. Stability and reactivity

Reactivity

No information available.

Chemical stability

Stable under recommended storage conditions

Possibility of hazardous reactions

None under normal use conditions

Conditions to Avoid

Do not freeze.

Incompatible materials

Strong oxidizing agents.

Hazardous decomposition products

No data available

11. Toxicological information

Acute toxicity

Information on likely routes of exposure

Product Information

- Inhalation:** Avoid inhalation.
- Eye contact:** May cause eye irritation.
- Skin contact:** May cause skin irritation.
- Ingestion:** Blood effects (may include anemia, neutropenia (decreased number of neutrophils), thrombocytopenia (decreased number of platelets), bone marrow depression).
Gastrointestinal effects (may include nausea/vomiting, abdominal pain, diarrhea, dry mouth, colic). Nervous system effects (headache, dizziness, light headedness). Hair loss.

Symptoms: No information available

Numerical measures of toxicity - Product Information

No information available

The following values are calculated based on chapter 3.1 of the GHS document

- Unknown acute toxicity** 100 % of the mixture consists of ingredient(s) of unknown toxicity
- 0 % of the mixture consists of ingredient(s) of unknown acute oral toxicity
- 100 % of the mixture consists of ingredient(s) of unknown acute dermal toxicity
- 100 % of the mixture consists of ingredient(s) of unknown acute inhalation toxicity (gas)
- 100 % of the mixture consists of ingredient(s) of unknown acute inhalation toxicity (vapor)
- 100 % of the mixture consists of ingredient(s) of unknown acute inhalation toxicity (dust/mist)

Component Information

Chemical Name	Oral LD50	Dermal LD50	Inhalation LC50
Cytarabine 147-94-4	> 5 g/kg (Rat)	-	-

Delayed and immediate effects as well as chronic effects from short and long-term exposure

- Corrosivity:** Not classified.
- Irritation:** Not classified.
- Sensitization:** Not classified.
- Mutagenic effects:** Contains a known or suspected mutagen.
- Carcinogenic effects:** Not classified.
- Reproductive toxicity:** Considered fetotoxic. Considered teratogenic. May cause harm to breastfed babies.
- STOT - single exposure:** Not classified.
- STOT - repeated exposure:** Not classified.
- Aspiration Hazard:** Not classified.

12. Ecological information

Ecotoxicity

No information available

Unknown aquatic toxicity

0 % of the mixture consists of component(s) of unknown hazards to the aquatic environment.

Chemical Name	Algae/aquatic plants	Fish	Toxicity to microorganisms	Crustacea
Cytarabine 147-94-4	-	-	-	-

Persistence and degradability

No information available.

Bioaccumulative potential

No information available.

Chemical Name	Partition coefficient
Cytarabine 147-94-4	-

Mobility

No information available

Other adverse effects

This product does not contain any known or suspected endocrine disruptors.

Chemical Name	EU - Endocrine Disruptors Candidate List	EU - Endocrine Disruptors - Evaluated Substances	Endocrine disrupting potential
Cytarabine 147-94-4	-	-	-

13. Disposal considerations

Waste treatment methods

Waste from residues/unused products

In accordance with local and national regulations

Contaminated Packaging

In accordance with local and national regulations

14. Transport information

ADG

Not regulated

IATA

Not regulated

IMDG

Not regulated

15. Regulatory information

Safety, health and environmental regulations/legislation specific for the substance or mixture

National regulations

Australia

See section 8 for national exposure control parameters

Standard for Uniform Scheduling of Medicines and Poisons (SUSMP)

No poisons schedule number allocated

International Inventories

TSCA	Does not comply
DSL/NDL	Does not comply
EINECS/ELINCS	Does not comply
ENCS	Does not comply
IECSC	Does not comply
KECL	Does not comply
PICCS	Does not comply
AICS	Does not comply
NZIOC	Complies

TSCA - United States Toxic Substances Control Act Section 8(b) Inventory

DSL/NDL - Canadian Domestic Substances List/Non-Domestic Substances List

EINECS/ELINCS - European Inventory of Existing Chemical Substances/European List of Notified Chemical Substances

ENCS - Japan Existing and New Chemical Substances

IECSC - China Inventory of Existing Chemical Substances

KECL - Korean Existing and Evaluated Chemical Substances

PICCS - Philippines Inventory of Chemicals and Chemical Substances

AICS - Australian Inventory of Chemical Substances

NZIOC - New Zealand Inventory of Chemicals and Chemical Substances

International Regulations

The Montreal Protocol on Substances that Deplete the Ozone Layer Not applicable

The Stockholm Convention on Persistent Organic Pollutants Not applicable

The Rotterdam Convention Not applicable

16. Other information

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Revision Note:
 Changes to Section 4.

Key or legend to abbreviations and acronyms

Legend Section 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

TWA	TWA (time-weighted average)
STEL	STEL (Short Term Exposure Limit)
Ceiling	Maximum limit value
*	Skin designation
C	Carcinogen

Key literature references and sources for data used to compile the SDS

Agency for Toxic Substances and Disease Registry (ATSDR)
 U.S. Environmental Protection Agency ChemView Database

European Food Safety Authority (EFSA)
EPA (Environmental Protection Agency)
Acute Exposure Guideline Level(s) (AEGl(s))
U.S. Environmental Protection Agency Federal Insecticide, Fungicide, and Rodenticide Act
U.S. Environmental Protection Agency High Production Volume Chemicals
Food Research Journal
Hazardous Substance Database
International Uniform Chemical Information Database (IUCLID)
Japan GHS Classification
Australia National Industrial Chemicals Notification and Assessment Scheme (NICNAS)
NIOSH (National Institute for Occupational Safety and Health)
National Library of Medicine's ChemID Plus (NLM CIP)
National Library of Medicine's PubMed database (NLM PUBMED)
National Toxicology Program (NTP)
New Zealand's Chemical Classification and Information Database (CCID)
Organization for Economic Co-operation and Development Environment, Health, and Safety Publications
Organization for Economic Co-operation and Development High Production Volume Chemicals Program
Organization for Economic Co-operation and Development Screening Information Data Set
RTECS (Registry of Toxic Effects of Chemical Substances)
World Health Organization

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End of Safety Data Sheet